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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,470	04/01/2005	Ulrich Mohr	7-4217	8227

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HOOKER & HABIB, P.C.
100 CHESTNUT STREET
SUITE 304
HARRISBURG, PA 17101

EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,470	MOHR ET AL.	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *121304*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "trumpetlike" in claims 57-80 is a relative term which renders the claim indefinite. The term "trumpetlike" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear if the term "trumpetlike" is to be used interchangeably with a term such as "flaring" or "conical" or any other such term that suggests a continuously increasing diameter. It is unclear what types of shapes are "trumpetlike" in configuration.

The term "large" in claim 73 is a relative term which renders the claim indefinite. The term "large" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Those of ordinary skill in the art would have differing views on what size pore diameters are considered "large." The specification offers little guidance on what degree of porosity is considered "large."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 57, 67 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramm (DE 19526533) – see provided English language translation.

Ramm discloses an apparatus for exposing a culture to a gaseous medium comprising a housing for holding a cell culture (Figure 1:6). The housing includes an upper cover part (Figure 1:1) and a lower base part (Figure 1:4). A flow duct (Figure 1:3) comprising an outflow opening is disposed above the surface of the culture. The fourth full paragraph on page 3 of the English translation indicates that the outflow opening of the flow duct is conical in shape. This conical configuration is considered to be "trumpetlike" in shape.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2) Claims 71, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramm (DE 19526533) – see provided English language translation.

Ramm discloses the apparatus as previously described above. Ramm, however, does not expressly indicate that the means for inducing air flow through the cell culture chamber is a suction device.

At the time of the invention, it would have been obvious to ensure that a suction device was used to move gases through the flow duct disclosed by Ramm. Suction means are functionally equivalent to other pumping devices in that each are known in the art as effective mechanisms capable of delivering air to a cell culture. Suction means provide the same services as other pumping systems, and are considered to be well known and implemented in the art.

3) Claims 57-69 and 71-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacoby (WO 0170927) - see provided English language translation in view of Paap (GB 1294466).

With respect to claims 57, 71, 78, 79 and 80, Jacoby discloses an apparatus and method for exposing a culture to a gaseous medium. Jacoby teaches that a housing having a top part and a bottom part is used to house a culture, and that a flow duct (Figure 2:40) is used to direct a flow of gaseous medium to the culture within the housing. The flow duct is disposed above the surface of the culture (Figure 2:23). This is taught on pages 2-4 and 8 of the English translation. A suction port (Figure 2:44) is used to draw gas through the flow duct and into the culture medium, and a second flow line (figure 2:39) is used to draw gaseous medium away from the culture medium. Jacoby, however, does not expressly state that the outflow opening of the flow duct is shaped in a trumpetlike configuration.

Paap discloses an apparatus for delivering a gas to a cell culture comprising a housing (Figure 1:12) and a flow duct (Figure 1:13) that includes an

outflow opening (figure 1:16) formed in a trumpetlike configuration. This is disclosed in columns 6 and 7.

Jacoby and Paap are analogous art because they are from the same field of endeavor regarding cell culture gas delivery devices.

At the time of the invention, it would have been obvious to alter the shape of the flow duct outlet opening disclosed by Jacoby in order to create a trumpetlike configuration. Paap teaches that the trumpetlike shape allows for effective aeration of a culture medium provided in a fluid. Alteration of the configuration of Jacoby's flow duct outlet represents a simple change in shape that would require only minor structural alterations that could be completed in a predictable manner. Using the teachings of Paap as a guide, it would have been obvious to alter Jacoby's outflow openings so that they flare outwardly at the ends.

With respect to claims 58 and 72, Jacoby and Paap disclose the apparatus set forth in claims 57 and 71 as set forth in the 35 U.S.C. 103 rejection above. Paap additionally teaches that the inner surface of the outflow opening is hyperboloid-shaped and rotationally symmetrical.

With respect to claims 59 and 61, Jacoby and Paap disclose the apparatus set forth in claim 57 as set forth in the 35 U.S.C. 103 rejection above. Figure 2 of Jacoby and Figure 1 of Paap each depict embodiments in which the housing comprises a wall enclosing a recess to receive a culture container

having an inner sidewall. In the Jacoby Figures, the annular gap between the inside sidewall and the rim of the outflow opening is shown as being less than the cross sectional area of the outflow opening. In the Paap Figures, the annular gap between the inside sidewall and the rim of the outflow opening is shown as being greater than the cross sectional area of the outflow opening.

With respect to claim 60, Jacoby and Paap disclose the apparatus set forth in claim 57 as set forth in the 35 U.S.C. 103 rejection above. Jacoby further states that the outflow opening is configured to be spaced a separation distance from the surface of the culture using selectively adjusting means. Figure 1 of Jacoby indicates that the gaseous flow ducts (40) are arranged vertically above the cell culture surfaces (22) on adjustable spindles (26). See page 7 of the English translation.

With respect to claim 62, Jacoby and Paap disclose the apparatus set forth in claim 57 as set forth in the 35 U.S.C. 103 rejection above. As mentioned above, a vacuum port (Figure 2:39) is in fluid communication with the cell culture in order to encourage the flow of gases through the cell culture from the flow duct.

With respect to claim 63, Jacoby and Paap disclose the apparatus set forth in claim 62 as set forth in the 35 U.S.C. 103 rejection above. Jacoby additionally indicates a bore extending into the housing to the chamber is

provided such that the flow duct is positioned at least partially within the bore. Page 9 of the translation indicates that an airtight seal is formed between the flow duct and the bore wall, thus dividing the bore into upstream and downstream portions. The vacuum line comprises a plurality of passages through the annular orifice fluidly communicating the upstream and downstream bore portions.

With respect to claim 64, Jacoby and Paap disclose the apparatus set forth in claim 63 as set forth in the 35 U.S.C. 103 rejection above. Jacoby additionally discloses the use of several flow deriving pipes (Figure 2:42) that are slipped over the flow ducts in order to form a plurality of annular orifices. The suction generated can be adjusted by changing the thicknesses of each flow deriving pipe.

With respect to claim 65, Jacoby and Paap disclose the apparatus set forth in claim 57 as set forth in the 35 U.S.C. 103 rejection above. Paap teaches in column 8, line 118 to column 9, line 4 that a heat exchange device is used to regulate the temperature of gaseous medium discharged from the flow duct.

With respect to claim 66, Jacoby and Paap disclose the apparatus set forth in claim 57 as set forth in the 35 U.S.C. 103 rejection above. Figure 2 of Jacoby indicates that a plurality of chambers and corresponding flow ducts are provided. Each flow duct is configured with a suction fitting and a supply of

gaseous medium. Paap likewise suggests processing multiple cell cultures in parallel using a plurality of chambers and flow ducts in column 5, lines 2-10.

With respect to claims 68 and 69, Jacoby and Paap disclose the apparatus set forth in claim 67 as set forth in the 35 U.S.C. 103 rejection above. Jacoby further states on pages 6 and 7 of the provided translation that means are provided for submersing the cell culture in a liquid medium.

With respect to claims 74-77, Jacoby and Paap disclose the apparatus set forth in claim 71 as set forth in the 35 U.S.C. 103 rejection above. Jacoby discloses that the flow duct arrangement comprises a plurality of branch lines (Figure 3:40) each in communication with the suction opening through a guide section (Figure 3:34). The guide section represents a common plenum shared by each flow duct branch line, and therefore serves to divide the air flow into a plurality of flow paths.

4) Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacoby (WO 0170927) - see provided English language translation in view of Paap (GB 1294466) as applied to claim 67, and further in view of Shin (US 7169355).

Jacoby and Paap disclose the apparatus set forth in claim 67 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that an ejection apparatus is provided for ejecting the container.

Shin discloses a microtiter plate housing comprising a plurality of chambers for accommodating a biological sample. An ejection means in the form of a spring (Figure 7:50) is provided for removing the housing. This is disclosed in column 2, lines 43-50.

Jacoby and Shin are analogous art because they are from the same field of endeavor regarding housing comprising a plurality of chambers adapted to accommodate a biological sample.

At the time of the invention, it would have been obvious to provide the Jacoby device with an ejection means capable of removing the container in the recess. Shin states that spring ejection systems are known in the art as a helpful means by which to remove individual chamber wells from an outer housing. The ejection system of Shin would have been beneficial if incorporated into Jacoby's system because it would have allowed for the removal of individual cell culture chambers without excessive manual manipulation.

5) Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacoby (WO 0170927) - see provided English language translation in view of Paap (GB 1294466) as applied to claim 67, and further in view of Curtis (US 6245555).

Jacoby and Paap disclose the apparatus set forth in claim 71 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a porous foamed material is used to cover the suction opening.

Curtis discloses a chamber (Figure 1:20) for culturing cells that comprises a flow duct (Figure 1:50) for introducing gases to the chamber volume. Curtis teaches in column 5, line 66 to column 6, line 10 that a porous filter is used to filter the gas before it is moved through the flow duct.

Jacoby and Curtis are analogous art because they are from the same field of endeavor regarding the delivery of gaseous mediums to cell culture systems.

At the time of the invention, it would have been obvious to add a porous filter to the gas introduction system disclosed by Jacoby. Curtis teaches that filters are well known in the art and beneficial for inhibiting the introduction of foreign contaminants into the system. Foam is considered to be a common filter construction material.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797